

REMARKS

Election/Restriction

Claims 3-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claims, there being no allowable generic or linking claim.

Specification

As suggested by the Examiner the title has been amended to recite a "Method Of Treating Osteoarthritis By Administering An IL-6 Antibody".

Claim rejections-35 USC § 101

Claim 13 is rejected under 35 U.S.C. 101 because the claimed invention is directed to nonstatutory subject matter.

Claim 13 has been presently cancelled.

Claim rejections-35 USC § 112, first paragraph

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner asserts that the antibody from the hybridoma with accession number CNTO 328, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public such as through deposit.

Applicant respectfully submits that the present specification is not the first disclosure of CNTO 328 and it is readily available to the public. The specification (page 3, lines 21-24) references CNTO 328 (also referred to as cCLB8) from van Zaanen et al (1998). CNTO 328 is a monoclonal antibody not a hybridoma and the numeration does not refer to an accession number as indicated by the Examiner. CNTO 328 (cCLB8) is also identified in numerous other publications including WO04/39826 (cited in IDS) where cCLB8 is fully

disclosed. Therefore, CNTO 328 is fully described and available to the public and the objection is moot.

Claim Rejections - 35 USC § 112, second paragraph

The Examiner objected to Claims 1-2, 6-13, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 1) Claim 1, line 2, is objected to as vague and indefinite because the limitation "a osteoarthritis" is improper.

Claim 1 has been amended to recite "osteoarthritis"

- 2) Claim 13, lines 2-3, is objected to as vague and indefinite for the recitation of "an anti-IL-6 receptor antibody" which is non-elected subjected matter.

Claim 13 has been cancelled herewith.

In light of the amendments to the claims the objection is moot.

Claim Rejections - 35 USC § 103

- a) Claims 1-2, 6-7, 9-13, are rejected under 35 U.S.C. § 103 as being unpatentable over Kishimoto et al (US Patent No. 5,888,510) in view of Raynauld et al. (2003).

The Examiner asserts Kishimoto et al. teach a method for inhibiting synovial cell growth by administering to a patient polyclonal or monoclonal antibodies to IL-6. but concedes Kishimoto et al. does not disclose a method of treating osteoarthritis by administering an IL-6 antibody. The Examiner asserts Raynauld et al teach that repeated injections of steroid to the knee of osteoarthritic patients is clinically effective for relief of symptoms of osteoarthritis but concedes that Raynauld et al. do not disclose a method of administering to a patient IL-6 antibodies to treat osteoarthritis. The Examiner argues Claim 1 recites the open language "comprising" which encompasses administering multiple medical agents. One would have been motivated to administer IL-6 antibodies and corticosteroids to a patient because Kishimoto et al teach the properties of IL-6 antibodies and Raynauld

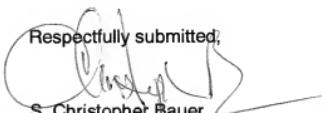
et al provides the motivation to administer corticosteroids to inhibit the inflammation caused by IL-6.

Without acquiescing on the merit of rejection Claim 1 has been amended to use "consisting of". As the Examiner freely admits neither Kishimoto et al. or Raynauld et al. do not disclose a method of administering to a patient IL-6 antibodies to treat osteoarthritis. In addition, Claims 11 and 12 have been recast as independent claims incorporating the limitations of Claim 1 using "consisting of". Also Claim 12 has been amended to delete "corticosteroids". It is respectfully submitted that in view of the amendments to the claims the rejection is moot.

b) Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kishimoto et al. (US Patent No. 5,888,510) in view of Raynauld et al. (2003) as applied to claims 1-2, 6, 9-13, above, and further in view in of Queen et al. (U.S. Patent No. 5,530,101). The Examiner relies on Queen to teach humanization of antibodies.

Queen et al. does not overcome the insufficiencies of Kishimoto et al. or Raynauld et al. with respect administering an IL-6 antibody to treat osteoarthritis and therefore in light of the amendment of claim 1 the rejection is moot.

No new matter has been added. Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.


Respectfully submitted;
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